

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

MEDTRONIC SOFAMOR DANEK USA, INC., WARSAW ORTHOPEDIC, INC., MEDTRONIC PUERTO RICO OPERATIONS CO., and MEDTRONIC SOFAMOR DANEK DEGGENDORF, GMBH	: : : : : : : : : :	CIVIL ACTION
v.		
GLOBUS MEDICAL, INC.	:	NO. 06-4248

OPINION

NORMA L. SHAPIRO, J.

July 16, 2009

This patent infringement action was filed by Medtronic Sofamor Danek USA, Inc. (“Medtronic USA”), Warsaw Orthopedic, Inc. (“Warsaw”), Medtronic Puerto Rico Operations Co. (“MPRO”) and Medtronic Sofamor Danek Deggendorf, GmbH (“Deggendorf”) against Globus Medical, Inc. (“Globus”) under 35 U.S.C. § 1, *et seq.* A jury found Globus liable for infringement; the parties stipulated to a bench trial on damages and injunctive relief. At the bench trial, plaintiffs presented evidence of injuries suffered by Medtronic USA, but not Warsaw, MPRO or Deggendorf. After the close of evidence, Globus filed a Post-Trial Brief arguing that Medtronic USA, MPRO and Deggendorf lacked constitutional standing to recover for infringement of the patents at issue. Medtronic USA, MPRO and Deggendorf contend they have standing, but in the alternative, request that the court re-open the evidentiary record on damages. This opinion will address: (1) plaintiffs’ request to re-open the evidentiary record; (2) constitutional standing of Warsaw, Medtronic USA, MPRO and Deggendorf; and (3) plaintiffs’ entitlement to damages and injunctive relief.

I. BACKGROUND

The United States Patent and Trademark Office issued United States Patent Numbers 6,530,929 (“the ‘929 patent”) and 7,008,422 (“the ‘422 patent”) to three inventors named on the patent applications: Kevin Foley, Michael Sherman and Jeff Justice. PX 1 (copy of ‘929 patent, issued March 11, 2003); PX 2 (copy of ‘422 patent, issued March 7, 2006). Foley, Sherman and Justice assigned title to SDGI Holdings, Inc.¹ PX 1; PX 2. Warsaw, created by the merger of SDGI Holdings, Inc. and Sofamor Danek Holdings, Inc., acquired title as SDGI Holdings, Inc.’s successor in interest. PX 17 (certificate of merger). Warsaw granted licenses to MPRO, Degendorf and Medtronic USA to practice certain aspects of the ‘929 and ‘422 patents. Warsaw, MPRO, Degendorf and Medtronic USA filed this action for infringement.²

The ‘929 and ‘422 patents pertain to devices and methods used by spinal surgeons to stabilize bony structures. PX 1; PX 2. Plaintiffs manufacture and market a commercial embodiment of the patented inventions called the Sextant System. Plaintiffs claimed Globus infringed by manufacturing, marketing and demonstrating a product called the Pivot System. After a 14-day trial on liability, a jury found the ‘929 and ‘422 patents valid and infringed by the Pivot System. See Interrogatories to the Jury with Answers Thereof (paper no. 235). Following unsuccessful settlement discussions, plaintiffs’ claims for damages and injunctive relief were

¹ Patents are assignable as personal property. 35 U.S.C. § 261.

² Plaintiffs alleged infringement of six patents. See Fourth Am. Compl. (paper no. 138). The court bifurcated trial of plaintiffs’ claims as provided by Federal Rule of Civil Procedure 42(b) (providing that, “[f]or convenience, to avoid prejudice, or to expedite and economize, the court may order a separate trial of one or more separate issues, claims, crossclaims, counterclaims, or third-party claims.”). Hr’g Tr., Apr. 15, 2008, p.12 (paper no. 121). The ‘929 and ‘422 patents were tried together by agreement of the parties; they pertain to related inventions. The other infringement claims have been settled.

presented to the court without a jury by agreement of the parties. At the bench trial, plaintiffs sought: (1) an award of \$2,866,405 for lost profits to compensate for Medtronic USA's sales of the Sextant System lost because of the infringement; (2) an award of \$1,327,866 for statutory royalties on sales of the Pivot System for which Medtronic USA did not claim lost profits; and (3) entry of a permanent injunction prohibiting Globus from selling the Pivot System. Plaintiffs' claims for lost profits and injunctive relief were based entirely on injuries to Medtronic USA; Warsaw, MPRO and Degendorf did not present evidence of lost profits or irreparable harm.

II. DISCUSSION

A. Plaintiffs' Request to Re-Open the Evidentiary Record

Plaintiffs, having obtained a verdict of infringement, sought recovery of damages and injunctive relief. In an action for patent infringement, a patentee may recover damages "adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court." 35 U.S.C. § 284. A patentee may also be entitled to injunctive relief. 35 U.S.C. § 283 ("The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.").

At trial, plaintiffs based their claims for lost profits and injunctive relief solely on evidence of injuries suffered by Medtronic USA. After the close of evidence, Globus submitted a Post-Trial Brief arguing that Warsaw was the only party with constitutional standing to recover

for patent infringement.³ Plaintiffs contend the evidence of record demonstrates Medtronic USA, MPRO and Degendorf have constitutional standing, but in the alternative, argue the evidentiary record should be re-opened to admit additional documents and testimony supporting their claim for damages.⁴ Plaintiffs argue they are entitled to present additional evidence because Globus untimely repudiated the parties' trial stipulation regarding ownership of the patents:⁵

³ Warsaw, having acquired title to the '929 and '422 patents, has standing to sue for patent infringement; the issue clouding the other plaintiffs' right to recover is whether Warsaw granted licenses conveying exclusionary rights sufficient to confer constitutional standing. See Part II.B.

⁴ Warsaw did not present evidence of irreparable harm to support a claim for injunctive relief and did not proffer such evidence in its request to re-open the record.

⁵ Plaintiffs request "that the Court re-open the record to allow it to address these issues, given that Globus stipulated to plaintiffs' standing until after the close of evidence." Pls.' Post-Trial Reply Br. at 5 n.6. Plaintiffs' request refers to a stipulation of the parties during the liability trial that Globus would not challenge plaintiffs' standing to sue for infringement:

Stipulation Regarding Ownership of U.S. Patent Nos. 7,008,422 and 6,530,929:
To facilitate the admission of evidence in an efficient manner and to obviate the need for testimony by custodians of record, IT IS HEREBY STIPULATED by and between the parties, acting through their counsel of record:

1. Plaintiff Warsaw is the owner, by assignment, of U.S. Patent Nos. 7,008,422 (the "'422 patent") and 6,530,929 (the "'929 patent"). Plaintiffs Medtronic USA, Inc., Medtronic Puerto Rico Operations, Co., and Medtronic Degendorf, GmbH are co-exclusive licensees of the '422 and '929 patents and, together with plaintiff Warsaw, share the exclusive right to bring suit for infringement of the patents.
2. The drawings bates numbered GLO00213-00295 represent the design of the Pivot approved for sale on September 22, 2006, when Medtronic filed the complaint against Globus.

(Paper no. 211.) The preamble and second numbered paragraph seem unrelated to the title of the stipulation and the first numbered paragraph, but the effect intended by the parties is clear: Globus agreed not to challenge plaintiffs' standing to sue for infringement. The stipulation was signed by the parties, but not signed or approved by the court. The court informed the jury of the

Globus's new argument that Medtronic USA lacks standing to recover damages for its lost Sextant sales reflects a basic misunderstanding of the way in which the '929 and '422 patents have been licensed. This misunderstanding is not entirely surprising: Globus took *no* discovery on this issue and, in fact, represented to the Court that it would not challenge Medtronic USA's standing to assert the '929 '422 patents in its pretrial brief. If there were truly any question as to the plaintiffs' standing to bring this lawsuit, one might have expected Globus to raise this issue sometime before the Court empanelled [*sic*] a jury for a three-week trial on liability.

Pls.' Post-Trial Reply Br. at 3.

Plaintiffs claim Globus "had never before mentioned, argued, or briefed this defense during two years of litigation,"⁶ but it is clear that plaintiffs recognized the standing problem earlier in the proceedings. Plaintiffs considered the standing implications of Warsaw's licensure of the patents in their pleadings:

Plaintiff Warsaw is the owner, by assignment, of the '422 patent [and '929 patent]. Plaintiffs Medtronic USA, Medtronic Puerto Rico, and Medtronic Deggendorf are coexclusive licensees of the '422 patent [and '929 patent] and, together with Plaintiff Warsaw, share the exclusive right to bring suit for infringement of the patent[s].

Fourth Am. Compl. ¶¶ 18, 24 (paper no. 139). Globus denied plaintiffs' standing allegations in its answer, see Am. Ans. ¶¶ 18, 24 (paper no. 122),⁷ but did not further assert the defense before trial. At the liability trial, plaintiffs remained sufficiently uncertain about their right to recover that they had Globus stipulate, word-for-word, to the standing allegations asserted in the Fourth Amended Complaint. Compare Stipulation (paper no. 211) with Fourth Am. Compl. ¶¶ 18, 24

stipulation at plaintiffs' request, but, as a matter of law, could not have submitted the issue of constitutional standing to the jury for decision.

⁶ Letter from plaintiffs' counsel to the court dated December 8, 2008.

⁷ Globus' Amended Answer to the Third Amended Complaint was deemed responsive to plaintiffs' Fourth Amended Complaint. Order of June 9, 2008 (paper no. 138).

(paper no. 132). Despite valid concern about their right to obtain relief, plaintiffs did not seek adjudication of constitutional standing before the close of evidence or present evidence preserving Warsaw's claim for damages. Instead, plaintiffs avoided the issue by procuring a stipulation on standing. Plaintiffs, under the mistaken assumption the standing issue would not resurface, then pursued relief solely on behalf of Medtronic USA, the party likely to have suffered the largest quantum of monetary damages and capable of presenting the most compelling case for injunctive relief.

But plaintiffs' reliance on the stipulation was unjustified because constitutional standing cannot be conferred by stipulation. See Part II.B. Each plaintiff could have presented evidence supporting its claims at trial or requested a ruling from the court. During the course of these proceedings, plaintiffs repeatedly sought rulings on matters of far less importance than constitutional standing; plaintiffs filed more than 20 motions concerning discovery, evidentiary and other matters. Given plaintiffs' willingness to approach the court for relief, their decision not to seek a ruling or present evidence supporting their right to recover suggests an attempt to avoid or delay adjudication of the issue.

Even if plaintiffs initially failed to appreciate the inherent risk of their strategy, they had notice of Globus' intent to challenge standing and an opportunity to preserve Warsaw's claims for lost profits and injunctive relief before the close of evidence. On October 28, 2008, *before* plaintiffs presented evidence of lost profits and irreparable harm in their case in chief, Globus deposed the vice president of Medtronic Corporate Development. Dep. of Shawn McCormick, Tr., p. 7 (Oct. 28, 2008). At the deposition, counsel for Globus referred the witness to PX 20, PX 21 and PX 22 (the documents proffered by plaintiffs as evidence of constitutional standing), and

inquired extensively into the written license and distribution agreements between Warsaw, MPRO, Degendorf and Medtronic USA. *Id.* at pp. 117 -26. This line of questioning placed plaintiffs on notice that Globus might assert a standing defense.

At the bench trial, counsel for Globus inquired into matters concerning ownership of the patents *before* plaintiffs presented evidence of Medtronic USA's lost profits and irreparable harm. Trial Tr., Oct. 30, 2008, p. 130 (cross-examination of plaintiffs' corporate designee during plaintiffs' case in chief). Plaintiffs' counsel objected to this inquiry and argued that Globus could not cross-examine the witness on matters pertaining to patent ownership because Globus had stipulated to plaintiffs' standing.⁸ Having been alerted that standing might become an issue, plaintiffs still proceeded by presenting evidence of lost profits and the need for injunctive relief of Medtronic USA, but not Warsaw, MPRO or Degendorf.

A valid stipulation entered into freely and fairly by the parties if approved by the court will not be set aside unless manifest injustice would result. *See Waldorf v. Shuta*, 142 F.3d 601, 617 (3d Cir. 1998). But the stipulation on which plaintiffs rely is not valid because it relates to constitutional standing, a jurisdictional requirement that cannot be conferred by stipulation of the parties. *See, e.g., Pandrol USA, LP v. Airboss Ry. Prods.*, 320 F.3d 1354, 1367 (Fed. Cir. 2003) ("any party, and even the court *sua sponte*, can raise the issue of standing for the first time at any stage of the litigation"). Plaintiffs concede the stipulation is unenforceable. *See* Trial Tr., May 11, 2009, p. 107 (paper no. 314).

⁸ "Your Honor, I object. This is all stipulated to. The ownership of the patents is one of the stipulations we read to the jury." Trial Tr., Oct. 30, 2008, p. 131 (objection sustained on grounds that the question inquired into matters beyond the scope of the witness's testimony on direct examination).

Plaintiffs' argument that Globus failed to challenge constitutional standing until after the close of evidence incorrectly suggests that plaintiffs lacked notice or opportunity to preserve Warsaw's claims for lost profits and injunctive relief at trial. Globus might have asserted the standing issue earlier in the proceedings,⁹ but it is plaintiffs' burden to establish standing. See Winer Family Trust v. Queen, 503 F.3d 319, 325 (3d Cir. 2007). The interest of justice is served when parties resolve disputes concerning standing at the beginning of civil litigation. While Globus was dilatory in bringing the issue to the court's attention, denial of plaintiffs' standing allegations in the pleadings was sufficient to notify plaintiffs the matter was in dispute.

When a party chooses not to present evidence at trial for strategic or tactical reasons, it is not an abuse of discretion to deny the party's request to re-open the record before entry of judgment. See Simon v. Shearson Lehman Bros., 895 F.2d 1304, 1323 (11th Cir. 1990).

Another district court confronted by a similar motion to re-open the record explained:

[A] party which has litigated the case under one legal theory generally should not be permitted to reopen in order to introduce evidence in support of another legal theory, or in support of issues not raised by that party at trial. If the party had an opportunity to litigate those issues, but chose not to, it should not be permitted to prolong the litigation any further. See Zenith Corp. v. Hazeltine Research Corp., 401 U.S. 321, 332, 91 S. Ct. 795, 28 L. Ed. 2d 77 (1971). Otherwise, no litigation would end, so long as a creative attorney could develop alternative theories of relief.

Bell Tel. Laboratories, Inc. v. Hughes Aircraft Co., 73 F.R.D. 16, 20 (D. Del. 1976) (denying a motion to re-open the record in a non-jury patent action prior to entry of judgment). See, e.g., Ball v. Interoceanica Corp., 71 F.3d 73, 76 (2d Cir. 1995) ("A trial court should not grant a new trial merely because the losing party can probably present a better case on another trial.").

⁹ At oral argument, counsel for Globus acknowledged he did not decide to challenge plaintiffs' standing until October, 2008. Trial Tr. May 11, 2009, p. 21 (paper no. 314).

Plaintiffs avoided the court's preliminary consideration of constitutional standing by asserting an unenforceable stipulation at the liability trial. Plaintiffs made further attempts to preclude consideration of standing by objecting to Globus' inquiry during the bench trial. Alerted to a likely challenge to constitutional standing before the close of evidence, plaintiffs failed to present evidence of lost profits and irreparable harm for plaintiffs other than Medtronic USA. No evidence of damages to other plaintiffs was offered but rejected. Plaintiffs' attempt to avoid adjudication of constitutional standing militates against re-opening the record for evidence that could have been presented at trial.

1. Plaintiffs' Proffer

After Globus asserted Medtronic USA, MPRO and Degendorf lacked standing, the court ordered plaintiffs to file a brief stating, with specificity, the nature and relevance of evidence they would present if the record were re-opened; Globus was given an opportunity to respond. Order of April 16, 2009 (paper no. 308). Plaintiffs proffered three categories of evidence: (1) documents and testimony purporting to confirm that Medtronic USA holds the exclusive right to distribute the patented products; (2) testimony purporting to confirm that all parties with an interest in the '929 and '422 patents have been named as plaintiffs; and (3) testimony purporting to confirm that all lost profits were suffered by Warsaw as well as Medtronic USA. Pl.'s Br. (paper no. 309). The court will re-open the record to admit evidence of patent ownership, but not evidence of Warsaw's lost profits.

a. Evidence of Patent Ownership and Licensure

The first category of plaintiffs' proffer is granted in part. The court will re-open the record to admit into evidence: (1) PX 17, Warsaw's certificate of merger, as evidence of

Warsaw's ownership of the '929 and '422 patents; and (2) PX 20, PX 21 and PX 22, the written license and distribution agreements granting patent rights to MPRO, Degendorf and Medtronic USA. Since the written license and distribution agreements are clear, unambiguous, and fully integrated, extrinsic evidence concerning their interpretation, including the proffered testimony, is inadmissible under the parol evidence rule. Because PX 18 and PX 19, Medtronic USA's distribution agreements with MPRO and Degendorf, are not evidence of exclusionary rights granted by Warsaw, they are inadmissible for lack of relevance.

b. Evidence Concerning Participation of Necessary Parties

The second category of plaintiffs' proffer is denied. Evidence concerning joinder of necessary parties relates to prudential standing, not constitutional standing. Determination that MPRO, Degendorf and Medtronic USA lack constitutional standing moots the question of prudential standing.

c. Evidence of Warsaw's Lost Profits

The third category of plaintiffs' proffer is denied. Plaintiffs seek to call witnesses who would testify that Warsaw suffered lost profits because it sold fewer components of the Sextant System to Medtronic USA as a result of the infringement. This testimony would be necessary for Warsaw to recover lost profits because the only evidence of record concerning lost profits relates to Medtronic USA; Warsaw cannot obtain relief for injuries suffered by Medtronic USA if Medtronic USA lacks constitutional standing.¹⁰ Evidence of Warsaw's lost profits will not be

¹⁰ In Poly-America, L.P. v. GSE Lining Tech., Inc., 383 F.3d 1303 (Fed. Cir. 2004), the court held that the patentee, Poly-America, could not recover damages for the lost profits of its non-exclusive licensee, Poly-Flex:

Even though Poly-America and Poly-Flex seem to share interests as two entities

admitted because it could have been presented at trial as plaintiffs now concede. At oral argument, Warsaw withdrew its claim for lost profits. Plaintiffs' counsel stated, "[W]e would not seek lost profits if Warsaw is the only party." Trial Tr. May 11, 2009, p. 39 (paper no. 314).

B. Constitutional Standing

Article III of the United States Constitution limits the judicial power of federal courts to resolution of actual "cases" and "controversies." U.S. Const. art. III, § 2. Constitutional standing requires that a plaintiff adequately establish:

(1) an injury in fact (*i.e.*, a concrete and particularized invasion of a legally protected interest); (2) causation (*i.e.*, a fairly traceable connection between the alleged injury in fact and the alleged conduct of the defendant); and (3) redressability (*i.e.*, it is likely and not merely speculative that the plaintiff's injury will be remedied by the relief plaintiff seeks in bringing suit).

Sprint Communs. Co., L.P. v. APCC Servs., 128 S. Ct. 2531, 2535 (2008) (internal quotations omitted). The instant dispute concerns only the injury in fact element of standing. A party's stake in litigation is sufficient to establish an injury in fact when "the constitutional or statutory

collaborating in the manufacture and sale of textured landfill liners, that relationship by itself is not sufficient to permit Poly-America to claim Poly-Flex's lost profits from Poly-Flex's lost sales. Poly-America and Poly-Flex have a common parent corporation and are not simply divisions of a single corporation, but are separate corporate entities. Their parent has arranged their corporate identities and functions to suit its own goals and purposes, but it must take the benefits with the burdens. While we do not speculate concerning the benefits that the two companies reap from dividing their operations and separating the owner of the patent from the seller of the patented product, Poly-America and Poly-Flex may not enjoy the advantages of their separate corporate structure and, at the same time, avoid the consequential limitations of that structure--in this case, the inability of the patent holder to claim the lost profits of its non-exclusive licensee. While Poly-America may have the right to sue under its patents, both as an owner and as a back-licensee, it can recover only its own lost profits, not Poly-Flex's.

Poly-America, 383 F.3d at 1311.

provision on which the claim rests properly can be understood as granting persons in the plaintiff's position a right to judicial relief." Warth v. Seldin, 422 U.S. 490, 500 (1975).

Constitutional standing is jurisdictional and cannot be waived by a party to suit. See United States v. Hays, 515 U.S. 737, 742 (1995) ("The question of standing is not subject to waiver. . ."); Evident Corp. v. Church & Dwight Co., 399 F.3d 1310, 1313 (Fed. Cir. 2005) (reviewing plaintiff's standing for the first time on appeal because "the issue whether an exclusive [patent] licensee lacked standing is jurisdictional and is not waived by a party's failure to raise the issue in the district court"); Mentor H/S, Inc. v. Medical Device Alliance, Inc., 240 F.3d 1016, 1018-19 (Fed. Cir. 2001). At the liability trial, the parties executed a stipulation concerning plaintiffs' standing to recover for infringement,¹¹ but the court must independently determine there is subject matter jurisdiction without regard to the parties' stipulation. See, e.g., Evident Corp., 399 F.3d at 1313.

1. Constitutional Standing to Sue for Patent Infringement

Congress has power "[t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." U.S. Const. art. I, § 8. The Patent Act authorizes the grant of a patent for inventions "not before known or used." Act of April 10, 1790, § 1, 1 Stat. 109. See Electric Storage Battery Co. v. Shimadzu, 307 U.S. 5, 11 (1939). As amended, the Patent Act now provides, "Whoever invents or discovers any new and useful process, machine, manufacture, or

¹¹ Stipulation Regarding Ownership of U.S. Patent Nos. 7,008,422 and 6,530,929, dated Sept. 21, 2008 (paper no. 211) ("Plaintiffs Medtronic USA, Inc., Medtronic Puerto Rico Operations Co., and Medtronic Deggendorf, GmbH are co-exclusive licensees of the '422 and '929 patents and, together with plaintiff Warsaw, share the exclusive right to bring suit for infringement of the patents.").

composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” 35 U.S.C. § 101. The rights bestowed by patent entitle the holder to exclude others from practicing the invention:

[The inventor] receives nothing from the law that he did not have before, and . . . the only effect of the patent is to restrain others from manufacturing and using that which he has invented . . . [T]he inventor could have kept his discovery to himself, but to induce a disclosure of it Congress has, by its legislation, made in pursuance of the Constitution, guaranteed to him an exclusive right to it for a limited time, and the purpose of the patent is to protect him in this monopoly - not to give him a use which he did not have before, but only to separate to him an exclusive use.

Continental Paper Bag Co. v. Eastern Paper Bag Co., 210 U.S. 405, 425 (1908). A patentee may enforce this right through a civil action for patent infringement. 35 U.S.C. § 271(a) (“Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.”); 35 U.S.C. § 281 (“A patentee shall have remedy by civil action for infringement of his patent.”). A federal district court has subject matter jurisdiction over actions for patent infringement under 28 U.S.C. §§ 1331 and 1338(a).

Constitutional standing to sue for patent infringement is established by ownership of and injury to the exclusionary rights bestowed by the patent grant. “Th[e] right to exclude is the legal interest created by statute. Constitutional injury in fact occurs when a party performs at least one prohibited action with respect to the patented invention that violates these exclusionary rights. The party holding the exclusionary rights to the patent suffers legal injury in fact under the statute.” Morrow v. Microsoft Corp., 499 F.3d 1332, 1339 (Fed. Cir. 2007). The Federal

Circuit Court of Appeals¹² recently explained:

There are three general categories of plaintiffs encountered when analyzing the constitutional standing issue in patent infringement suits: those that can sue in their own name alone; those that can sue as long as the patent owner is joined in the suit; and those that cannot even participate as a party to an infringement suit.

The first category includes plaintiffs that hold all legal rights to the patent as the patentee or assignee of all patent rights - the entire bundle of sticks. Unquestionably, a patentee who holds all the exclusionary rights and suffers constitutional injury in fact from infringement is one entitled to sue for infringement in its own name. Additionally, if a patentee transfers all substantial rights to the patent, this amounts to an assignment or a transfer of title, which confers constitutional standing on the assignee to sue for infringement in its own name alone. When a party holds all rights or all substantial rights, it alone has standing to sue for infringement.

The second category of plaintiffs hold exclusionary rights and interests created by the patent statutes, but not all substantial rights to the patent. As the grantee of exclusionary rights, this plaintiff is injured by any party that makes, uses, sells, offers to sell, or imports the patented invention. Parties that hold the exclusionary rights are often identified as exclusive licensees, because the grant of an exclusive license to make, use, or sell the patented invention carries with it the right to prevent others from practicing the invention. However, these exclusionary rights must be enforced through or in the name of the owner of the patent, and the patentee who transferred these exclusionary interests is usually joined to satisfy prudential standing concerns.¹³ The patentee is joined for the

¹² Decisions of the Federal Circuit Court of Appeals are binding on this court on matters of patent law. 28 U.S.C. § 1295 (a)(1) (conferring Federal Circuit Court of Appeals with exclusive jurisdiction over “an appeal from a final decision of a district court of the United States . . . if the jurisdiction of that court was based, in whole or in part, on section 1338 of this title”).

¹³ A patent infringement plaintiff must establish both constitutional and prudential standing. Morrow, 499 F.3d at 1338. Constitutional standing requires that a licensee have exclusive rights under the patent. Prudential standing requires that an exclusive licensee with constitutional standing join the patentee as co-plaintiff. See Int’l Gamco, Inc. v. Multimedia Games, Inc., 504 F.3d 1273, 1278-79 (Fed. Cir. 2007) (“[T]his court’s prudential standing requirement compels an exclusive licensee with less than all substantial rights, such as a field of use licensee, to join the patentee before initiating suit.”); Prima Tek II, L.L.C. v. A-Roo Co., 222 F.3d 1372, 1377 (Fed. Cir. 2000). Like constitutional standing, prudential standing is jurisdictional and cannot be waived. Mentor H/S, Inc. v. Medical Device Alliance, Inc., 240 F.3d

purpose of avoiding the potential for multiple litigations and multiple liabilities and recoveries against the same alleged infringer . . .

The third category of plaintiffs includes those that hold less than all substantial rights to the patent and lack exclusionary rights under the patent statutes to meet the injury in fact requirement. They are not injured by a party that makes, uses, or sells the patented invention because they do not hold the necessary exclusionary rights. Plaintiffs in this category lack constitutional standing. This standing deficiency cannot be cured by adding the patent title owner to the suit.

Morrow, 499 F.3d at 1339-41 (footnotes, quotations and citations omitted).

An exclusive license is one in which the patentee transfers its entire right to exclude others from practicing a specific aspect of the patented invention. “To be an exclusive licensee for standing purposes, a party must have received, not only the right to practice the invention within a given territory, but also the patentee’s express or implied promise that others shall be excluded from practicing the invention within that territory as well.” Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1552 (Fed. Cir. 1995). The patentee’s promise of exclusivity is essential. “Thus, if a patentee-licensor is free to grant licenses to others, licensees under that patent are not exclusive licensees.” Textile Prods. v. Mead Corp., 134 F.3d 1481, 1484 (Fed. Cir. 1998) (internal quotation omitted). In Textile Products, the licensee lacked constitutional standing because the patentee had “retained for itself important rights to license the invention to others.” Textile Prods., 134 F.3d at 1484. Absent a promise of exclusivity from the patentee, a licensee does not have standing merely because it holds the only license granted by the patentee. Bicon, Inc. v. Straumann Co., 441 F.3d 945, 956 (Fed. Cir. 2006) (licensee lacked standing because its “right to practice the patent was ‘exclusive’ only in the sense that [it] was the only licensee of the

1016, 1018 (Fed. Cir. 2001) (“[T]he issue of whether an exclusive licensee has sufficient rights in a patent to bring suit in its own name is jurisdictional and, therefore, is not waived by a party’s failure to raise the issue in the district court.”).

. . . patent at the time ”). An exclusive licensee must have ultimate authority to decide whether others may practice the invention. See, e.g., Propat International Corp. v. RPost US, Inc., 473 F.3d 1187, 1194 (Fed. Cir. 2007) (licensee lacked standing because the patentee had retained the right to veto the licensee’s grant of sub-licenses); Morrow, 499 F.3d at 1342 (licensee lacked standing because it did “not have the right to license or sublicense or otherwise forgive activities that would normally be prohibited under the patent statutes”).

A patentee’s reservation of exclusionary rights can render a license agreement non-exclusive. In Purdue Pharma Prods. L.P. v. Par Pharm., Inc., Civil Action No. 07-255, 2008 U.S. Dist. LEXIS 98178 (D. Del. Dec. 3, 2008), the patentee granted two licenses to practice the patent, but reserved the right to grant further licenses. The patentee, joined by one of the licensees, sued for infringement. Circuit Judge Jordan, sitting by designation in the District of Delaware, held the patentee’s reservation of the right to grant additional licenses was “sufficient to undermine [the licensee’s] claim of standing, since the Federal Circuit has held that a licensee lacks standing to sue when even one other entity has the patentee’s permission to practice the patent in the applicable territory, irrespective of whether others might be excluded.” Purdue Pharma, 2008 U.S. Dist. LEXIS 98178 at *7 (citing Mars, Inc. v. Coin Acceptors, Inc., 527 F.3d 1359, 1368 (Fed. Cir. 2008)). See also Weinart v. Rollform, Inc., 744 F.2d 797, 807 (Fed. Cir. 1984) (standing established where licensee “had an exclusive right to sell as *sole* distributor in the United States”) (emphasis added).

Plaintiffs contend MPRO, Deggendorf and Medtronic USA hold “co-exclusive” licenses to practice the patents. The Federal Circuit has used the term “co-exclusive license” only once in a reported opinion. See Rhone-Poulenc Agro Sa v. Dekalb Genetics Corp., 272 F.3d 1335, 1342

(Fed. Cir. 2001) (“Monsanto paid \$8 million in return for a co-exclusive license to the Comai patents, shared in part with DeKalb, for use in all fields.”). In Rhone-Poulenc, the court did not consider whether Monsanto or DeKalb, the co-licensees, had standing to sue for patent infringement because neither claimed infringement. However, when Monsanto did sue later for patent infringement, the district court held Monsanto lacked standing. The district court found the “‘co-exclusive’ licenses amounted to nothing more than nonexclusive licenses, which confer no standing on a party to bring or even join a suit for infringement.” Monsanto Co. v. Aventis Cropscience Sa, 226 F. Supp. 2d 531, 539 (D. Del. 2002).

Plaintiffs contend Monsanto is distinguishable because Monsanto shared its “co-exclusive” license with a competitor, but Warsaw, MPRO, Degendorf and Medtronic USA are related corporate entities. See Pls.’ Post-Trial Reply Br. at 4 n.4 (“The field of use licenses to MPRO and Degendorf contain an express covenant by Warsaw not to grant any licenses *to non-Medtronic entities*. . . . Medtronic USA is the exclusive holder of the right to distribute products embodying the ‘929 and ‘422 patents, and *all of the parties are related entities*.”) (emphasis added). However, Monsanto and DeKalb, the original co-licensees in Monsanto, were related corporate entities. Rhone-Poulenc Agro, S.A. v. DeKalb Genetics Corp., 271 F.3d 1081, 1083 (Fed. Cir. 2001) (noting that Monsanto and DeKalb collaborated on research and development of the patents and shared common ownership). Although DeKalb was acquired by a competitor before Monsanto filed suit for infringement, Monsanto lacked standing because the *original* license agreement failed to convey “all substantial rights” in the patents within the area of exclusivity. Monsanto, 226 F. Supp. 2d at 535-36, 539. Monsanto is not binding on this court but is persuasive authority that constitutional standing is determined by the exclusionary rights

held by the licensee, not by the relationship among co-licensees. Plaintiffs' argument misconstrues property rights bestowed by the patent grant because it implies that a patentee may grant multiple "co-exclusive" licenses so long as all licensees lack an incentive to exclude each other.

Plaintiffs argue the Federal Circuit implicitly recognized "co-exclusive" licensee standing in Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A., 944 F.2d 870 (Fed. Cir. 1991). In Vaupel, the patentee effectively assigned all substantial rights in the patent to two purportedly exclusive licensees. The court held the patentee's *de facto* assignment conferred standing to sue for infringement on the assignees without joining the patentee as a necessary party: "We conclude that the subject agreements here, although not constituting a formal assignment of the U.S. patent, were a grant of all substantial rights and, in accordance with [Federal Rule of Civil Procedure] 19, permitted [Vaupel KG and Vaupel NA] to sue without joining Marowsky [the patentee]." Vaupel, 944 F.2d at 874. Vaupel KG and Vaupel NA were exclusive licensees with standing to sue for infringement because the patentee granted both the right "to protect the invention covered by the patent against encroachment by third parties." Vaupel, 944 F.2d at 874. Holding the right to exclude third parties dispositive of the right to sue for infringement, the court explained that "the agreements expressly granted [the licensees] the *sole* right to sue for all infringements, past, present, and future as well." Id. at 876 (emphasis added) ("The final decision, whether or not a particular party is to be sued lies . . . solely with Vaupel KG and Vaupel NA].").

Vaupel is consistent with recent Federal Circuit authority holding that a licensee lacks constitutional standing if it does not possess exclusive rights to exclude others from practicing

the invention. In Mars, Inc. v. Coin Acceptors, Inc., 527 F.3d 1359 (Fed. Cir. 2008), MEI (the purported exclusive licensee) lacked constitutional standing because Mars (the patentee) had granted MEI-UK (a corporate subsidiary of Mars) rights to practice the same aspects of the patent:

In the 1996 Agreements, Mars and MEI agreed that Mars was the owner of the patents-in-suit:

[Mars] currently owns a substantial number of patents and patent applications, which existed at 31 December 1995, relating to [patented] Products . . . manufactured and sold by MEI-UK.

In the same document, Mars made clear that MEI-UK – a separate corporate entity from either Mars or MEI – previously had and would continue to have a license to practice the patents-in-suit:

MEI-UK will continue to have a non-exclusive right to exploit, in the conduct of its business, the Covered Intellectual Property in any country of the world in exchange for a royalty payable to [Mars].

Thus, prior to 1996, MEI-UK had a license: the right to practice the patents-in-suit “in any country of the world” (including the United States), in exchange for a royalty payment. MEI cannot have been Mars’s exclusive United States licensee, when the terms of the 1996 Agreements make clear that Mars had allowed MEI-UK to practice the patents in the United States. The deposition testimony of Mars’s Corporate Tax Director confirmed MEI-UK’s rights under its license from Mars. *See* J.A. 4130 (“Q. Were there instances where MEI-U.K. could make a product such as a coin changer and import that product into the United States for delivery to MEI, Inc.? A. That could happen, sure.”).

Mars Inc., 527 F.3d at 1368. The court held that “if the patentee *allows* others to practice the patent in the licensee’s territory, then the licensee is *not* an exclusive licensee.” Id. at 1368 (emphasis in original).

Plaintiffs argue, “In patent cases, standing analysis avoids the situation in which a single infringer could be ‘harassed by a multiplicity of suits instead of one, and [subjected] to

successive recoveries of damages by different persons holding different portions of the patent-right.’ No such concern exists here.” Pls.’ Post-Trial Reply Br. at 3 (quoting Pope Mfg. Co. v. Gormully & Jeffery Mfg. Co., 144 U.S. 248, 251 (1892)). This characterization of the standing requirement blurs the distinction between the independent requirements of constitutional and prudential standing. See Morrow, 499 F.3d at 1338 (“[T]o have standing, [a licensee] must meet both constitutional and prudential standing requirements.”). The analysis of prudential standing in Pope Manufacturing relates to the presence of necessary parties, not the injury in fact element of constitutional standing. Pope Mfg., 144 U.S. at 252 (exclusive licensee must join the patentee in an action for patent infringement). See Int’l Gamco, Inc. v. Multimedia Games, Inc., 504 F.3d 1273, 1278 (Fed. Cir. 2007) (“Courts and commentators have relied on Pope for the proposition that an exclusive field of use licensee does not have standing to sue in its own name without joining the patent holder.”).

Here, the matter in dispute is not whether MPRO, Deggendorf and Medtronic USA have standing to sue for infringement without joining Warsaw, the patent holder, but whether each plaintiff independently satisfies the constitutional standing element of injury in fact. A licensee who has not suffered an injury in fact cannot acquire constitutional standing by joining the patent holder as a co-plaintiff. See Propat, 473 F.3d at 1193-94 (“A bare licensee cannot cure its lack of standing by joining the patentee as a party.”).¹⁴

¹⁴ Plaintiffs rely on Pandrol USA, LP v. Airboss Ry. Prods., 320 F.3d 1354 (Fed. Cir. 2003), for their argument that an exclusive licensee has constitutional standing to sue for infringement when joined by the patentee as a co-plaintiff. While the exclusive licensee in Pandrol was held to have satisfied the constitutional standing requirement, the court did not describe the terms of the license agreement or analyze the grant of exclusionary rights in its opinion. Pandrol, 320 F.3d at 1368. Plaintiffs’ reliance on Pandrol is not persuasive because the opinion does not analyze the licensee’s alleged exclusionary rights.

2. Interpretation of the License and Distribution Agreements

The rights conferred by the license and distribution agreements determine constitutional standing. See Ortho Pharmaceutical Corp. v. Genetics Inst., 52 F.3d 1026, 1033 (Fed. Cir. 1995) (where district court offered no analysis supporting its conclusion that license agreements pertained to the patent-in-suit, appellate court inquired into the subject matter of the license agreements before considering plaintiffs' standing as exclusive licensees). Morrow, 499 F.3d at 1340 n.7 (“[I]n determining whether a party holds the exclusionary rights, we determine the substance of the rights conferred on that party, not ... the characterization of those rights as exclusive licenses or otherwise.”); Textile Prods. v. Mead Corp., 134 F.3d 1481, 1484 (Fed. Cir. 1998). “[T]he general rules of construction for contracts are applicable to the construction of patent licenses. The construction of patent license agreements is governed by state law.” 6 Lipscomb, Walker on Patents § 20:58 at 202 (1987). See Ortho Pharm., 52 F.3d at 1033 (Fed. Cir. 1995); Intel Corp. v. United States Int’l Trade Comm’n, 946 F.2d 821, 826 (Fed. Cir. 1991).

The license and distribution rights granted by Warsaw (PX 20, PX 21 and PX 22) govern whether MPRO, Degendorf and Medtronic USA hold exclusionary rights in the patents necessary to establish constitutional standing. The agreements with Warsaw grant MPRO, Degendorf and Medtronic USA patent rights related to products in the spinal and cranial medical field. The agreements do not explicitly mention the ‘929 or ‘422 patents, but the agreements do pertain to the ‘929 and ‘422 patents.¹⁵ See PX 20 at MSD0718493; PX 21 at

¹⁵ While the written agreements do not explicitly mention the ‘929 or ‘422 patents, there is circumstantial evidence of MPRO’s, Degendorf’s and Medtronic USA’s rights under those patents. The agreements grant rights pertaining to medical devices and products that relate to the patented technology. Globus acknowledged that the agreements relate to the ‘929 and ‘422 patents. “Based on the rights granted by Warsaw in this [*sic*] agreements, Medtronic USA,

MSD0718502; PX 22 at MSD0718512.

The Warsaw agreements provide for application of Minnesota and Tennessee state law. Contractual choice of law provisions are enforceable to the extent permitted by the law of the forum state and the United States Constitution. Under Pennsylvania law, “when a transaction bears a reasonable relation to this Commonwealth and also to another state or nation, the parties may agree that the law either of this Commonwealth or of such other state or nation shall govern their rights and duties.” 13 Pa.C.S. § 1301. See Gay v. CreditInform, 511 F.3d 369, 390 (3d Cir. 2007) (“Pennsylvania courts will uphold choice-of-law provisions in contracts to the extent that the transaction bears a reasonable relation to the chosen forum.”). “[F]or a State’s substantive law to be selected in a constitutionally permissible manner, that State must have a significant contact or significant aggregation of contacts, creating state interests, such that choice of its law is neither arbitrary nor fundamentally unfair.” Allstate Ins. Co. v. Hague, 449 U.S. 302, 312-13 (1981).

Warsaw’s license agreements with MPRO and Deggendorf provide for application of Minnesota law. PX 20 at MSD0718499; PX 21 at MSD0718508. The license agreements are reasonably related to Minnesota because they govern rights granted and retained by Warsaw, which maintains a presence and accepts service of process in Minnesota: “The Secretary of State shall mail any such process to [Warsaw] at 710 Medtronic Parkway, Minneapolis, Minnesota 55432.” PX 17 at MSD0051240. Minnesota law provides that a contract is construed according

Medtronic Puerto Rico, and Deggendorf . . . are not exclusive licensees. As set forth in their respective agreements, all three of them have the right to practice some or all of the aspects of the rights under the ‘422 and ‘929 Patents . . .” Def.’s Tr. Br., p. 7 (paper no. 297). The intellectual property described in PX 20, PX 21 and PX 22 includes rights under the ‘422 and ‘929 patents.

to the unambiguous meaning of its terms. A contract is unambiguous unless, based upon its language alone, it is reasonably susceptible of more than one interpretation. Whether a contract is ambiguous is a question of law. See Denelsbeck v. Wells Fargo & Co., 666 N.W.2d 339, 346 (Minn. 2003).

Warsaw's distribution agreement with Medtronic USA provides for application of Tennessee law. PX 22 at MSD0718518. The distribution agreement is reasonably related to Tennessee because it governs the rights granted to Medtronic USA, a Tennessee corporation. Tennessee law provides, "If the contract language is unambiguous, the written terms control, not the unexpressed intention of one of the parties." 94th Aero Squadron of Memphis, Inc. v. Memphis-Shelby County Airport Auth., 169 S.W.3d 627, 634 (Tenn. Ct. App. 2004).

a. Standing of MPRO and Degendorf

Warsaw entered into separate, nearly identical license agreements granting MPRO and Degendorf "co-exclusive" licenses for manufacturing. PX 20; PX 21. The relevant portions of the license agreements provide:

- "Licensor is the owner or exclusive licensee of all right, title and interest in certain Intellectual Property Rights relating to the Product."¹⁶ PX 20 at MSD0718492; PX 21 at MSD0718501.
- "Licensee is skilled in the manufacture of medical devices [and] desires to use the

¹⁶ The agreements do not define "Intellectual Property Rights," but define "Product" as "that product manufactured by Licensee in the spinal and cranial medical field. This shall include attached locking mechanisms, screws (fixed angle, variable angle, break-off set, and all other), hooks (wide blade, large pedicle, right angled, and all other), rods (smooth, super flex, commercially pure, and all other), spinal cages and other spinal and cranial product as specifically designated by the Licensor and agreed to by Licensee." PX 20 at MSD0718493; PX 21 at MSD0718502.

Intellectual Property Rights in the Territory.”¹⁷ PX 20 at MSD0718492; PX 21 at MSD0718501.

- “Whereas, Licensor is willing to grant to Licensee the Co-exclusive right to use the Intellectual Property Rights in the Territory, subject to the terms and conditions of this Agreement, and Licensee is willing to accept such rights and obligations; . . . Licensor grants to Licensee the Co-exclusive right to use, develop, enjoy, and enforce the Intellectual Property Rights for the purpose of manufacturing Product for sale in the Territory subject to the terms and conditions of this Agreement. Licensor agrees that it will not license or sublicense the Intangible Property¹⁸ to any unrelated licensee, that is, any entity who is not a subsidiary, parent or commonly owned entity or affiliate, other than as provided [herein].” PX 20 at MSD0718492-4; PX 21 at MSD0718501-3.
- “The parties acknowledge that it may be necessary for Licensor to grant a license to a third party for some portion of the Intangible Property in the Territory as a result of a judicial decree or other similar circumstance, such as in settlement of litigation alleging patent infringement by the Licensor. As part of this Agreement, Licensee consents to such third party licensing by Licensor under such circumstances.” PX 20 at MSD0718494; PX 21 at MSD0718503.
- “Licensee shall not assign, sublicense, make available or otherwise transfer or disclose any right to use, develop, or otherwise enjoy the Intangible Property, other than as required [herein], without the express written consent of Licensor except as otherwise provided for herein.” PX 20 at MSD0718494; PX 21 at MSD0718503.
- “Licensee may, from time to time, permit the manufacture of Product through a manufacturing facility owned by Licensor or by an Affiliate¹⁹ or Licensor in order to

¹⁷ “Territory” is defined as “the entire world.” PX 20 at MSD0718493; PX 21 at MSD0718502.

¹⁸ “Intangible Property” is defined as “Licensor developed inventions, secret processes, technical information, and technical expertise relating to the design of Product and all legal rights associated therewith, including without limitation, patents, trade secrets, know-how, copyrights and all Regulatory Approvals associated with Product.” PX 20 at MSD0718493; PX 21 at MSD0718502.

¹⁹ The agreements define “Affiliate or Affiliates” as “any corporation, firm, partnership, or other entity, whether de jure or de facto, that directly or indirectly owns, is owned by, or is under common ownership with a party to this Agreement to the extent of at least 50 percent of the equity having the power to vote on or direct the affairs of the entity and any person, firm, partnership, corporation, or other entity actually controlled by, controlling, or under common control with a party to this Agreement.” PX 20 at MSD0718492; PX 21 at MSD0718501.

insure an uninterrupted supply of Product in the Territory.” Id.

- “Licensee shall pay to Licensor a royalty ... of Licensee’s Net Sales of Product in the Territory.” PX 20 at MSD0718494; PX 21 at MSD0718503.
- “‘Net Sales’ shall mean the gross receipts from Product sold by Licensee to Affiliates and to unrelated parties” PX 20 at MSD0718493; PX 21 at MSD0718502.
- “Licensee acknowledges Licensor’s exclusive right, title, and interest in and to the Intangible Property.” PX 20 at MSD0718496; PX 21 at MSD0718505.
- “Licensor will assist Licensee or its authorized representative in connection with any action initiated to suppress any infringement or violation of any Intangible Property or otherwise enforce any right associated with the Intangible Property.” PX 20 at MSD0718496; PX 21 at MSD0718505.
- “Licensor does not have authority to act as agent or to make representations or create obligations on behalf of Licensee. Licensee does not have authority to act as agent or to make representations or create obligations on behalf of Licensor.” PX 20 at MSD0718496; PX 21 at MSD0718505.

The license agreements are clear and unambiguous. MPRO and Deggendorf claim they hold “co-exclusive” licenses for manufacturing, but Warsaw expressly reserved for itself the right to manufacture products covered by the patents and to grant manufacturing licenses to its subsidiaries, parents, commonly owned entities and affiliates. Because MPRO and Deggendorf cannot sub-license their manufacturing rights, Warsaw has reserved ultimate authority over the manufacture of the patented inventions. The agreements do not transfer sufficient exclusionary rights to confer standing on MPRO or Deggendorf to sue for infringement. MPRO and Deggendorf lack constitutional standing to sue for patent infringement and will be dismissed with prejudice.

b. Standing of Medtronic USA

Warsaw and Medtronic USA are parties to a distribution agreement granting Medtronic

USA a “co-exclusive” license to distribute products covered by the patents. The relevant portions of the distribution agreement provide:

- “Warsaw hereby appoints [Medtronic] USA as a distributor of its Products in the Territory, and [Medtronic] USA hereby accepts such appointment.” PX 22 at MSD0718512.
- “Warsaw grants to [Medtronic] USA the co-exclusive license to use and to sell within the Territory²⁰ Products²¹ covered by patents and other intellectual property rights Warsaw owns or has the exclusive right to enforce as an exclusive licensee. Warsaw also grants [Medtronic] USA the co-exclusive right to enforce said patents and intellectual property rights within the Territory together with Warsaw.” PX 22 at MSD0718512.
- “[Medtronic] USA shall not have the right or power to assign any of its rights, or delegate the performance of any of any [*sic*] of its duties under this Agreement without the prior written authorization of Warsaw, provided, however, that such prior written authorization shall not be required for [Medtronic] USA to assign any of its rights and or delegate the performance of any of its duties hereunder, to any existing or newly formed subsidiary²² for purposes of marketing and distributing the Products.” PX 22 at MSD0718517.
- “[Medtronic] USA shall be allowed to appoint sub-distributors, dealers, retailers or other non-employee representatives to work in connection with the distribution of the Products in the Territory upon approval of Warsaw. Warsaw shall not unreasonably withhold such approval.” PX 22 at MSD0718512.
- “Warsaw or its designee shall sell the Products to [Medtronic] USA at the prices and discounts negotiated agreed [*sic*] to by Warsaw and [Medtronic] USA.” PX 22 at MSD0718514.

The distribution agreement is clear and unambiguous. Plaintiffs claim that “Medtronic USA is the *only* entity licensed by the patent owner, Warsaw, to distribute products that embody

²⁰ “Territory” is defined as “the entire world.” PX 22 at MSD0718512.

²¹ “Products” are defined as “that product manufactured by Warsaw in the spinal and cranial medical field. This shall include peek product.” PX 22 at MSD0718512.

²² “Subsidiary” is defined as “any entity or association controlled by, controlling or under common control of, a party to this Agreement. For the purposes of this Agreement, the term ‘control’ shall mean the ownership of at least 50% of the voting stock or other equity interest in any entity or association.” PX 22 at MSD0718512.

the inventions claimed in the ‘929 and ‘422 patents.” Pls.’ Post-Trial Reply Br. at 3 (emphasis in original). However, the distribution agreement appoints Medtronic USA as “a” distributor of the patented products, not the sole distributor. Even if Medtronic USA were the only distributor appointed by Warsaw, this alone would be insufficient to establish standing. Bicon, Inc., 441 F.3d at 956.

Absent from the distribution agreement is any express or implied promise that Warsaw will refrain from appointing other distributors. The absence of such a promise requires the determination that Medtronic USA’s license is not exclusive.²³ See Rite-Hite, 56 F.3d at 1552 (“To be an exclusive licensee for standing purposes, a party must have received, not only the right to practice the invention within a given territory, but also the patentee’s express or implied promise that others shall be excluded from practicing the invention within that territory as well.”).

Medtronic USA’s distribution rights are also non-exclusive because Warsaw granted MPRO and Degendorf unqualified rights to sell patented products to “unrelated parties” in

²³ The court need not inquire into the existence of collateral agreements between Warsaw and Medtronic USA because the distribution agreement contains an entirety clause:

This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements, understandings and communications, whether written or oral, between the parties with respect to the subject matter hereof. No modification or amendment of this Agreement shall be effective unless in writing and executed by a duly authorized representative of each party.

PX 22 at MSD0718518. Plaintiffs have not submitted any written amendments to the Distribution Agreement.

exchange for royalty payments.²⁴ See PX 20 at MSD0718493; PX 21 at MSD0718502. The license agreements do not support plaintiffs' claim that Warsaw required MPRO and Deggendorf to retain Medtronic USA as their sole distributor.²⁵ The license agreements between MPRO, Deggendorf, and Warsaw do not mention Medtronic USA (or Medtronic USA's distribution rights) or otherwise impose restrictions regarding the parties to whom MPRO and Deggendorf may sell. Warsaw's distribution agreement with Medtronic USA does not mention MPRO or Deggendorf (or their rights to sell patented products to "unrelated parties"). The distribution agreement provides that Medtronic USA will purchase products from Warsaw, not MPRO or Deggendorf. Even though MPRO and Deggendorf may have independently chosen to appoint Medtronic USA as their distributor, nothing in the license agreements with Warsaw required them to do so. Because Warsaw allowed MPRO and Deggendorf to sell the patented products to unrelated parties, Medtronic USA's distribution rights cannot have been exclusive. See Mars, Inc., 527 F.3d at 1368 ("[The licensee] cannot have been [the patentee's] exclusive United States licensee, when the terms of the 1996 Agreements make clear that [the patentee] had allowed [another licensee] to practice the patents in the United States.").

Medtronic USA lacks other important indicia of ownership relevant to constitutional standing, *e.g.*, the right to transfer its interest in the patents. Medtronic USA cannot assign its

²⁴ The Warsaw agreements prohibit MPRO and Deggendorf from sub-licensing or assigning their manufacturing rights, PX 20 at MSD0718494; PX 21 at MSD0718503, but allow MPRO and Deggendorf to sell products they manufacture to unrelated parties, PX 20 at MSD0718493; PX 21 at MSD0718502.

²⁵ Plaintiffs argue, "Warsaw gives MPRO and Deggendorf the exclusive right to use, develop, enjoy, and enforce for the purpose of manufacturing. It doesn't give them a right to sell for distribution. . . . The only right they have is this right of manufacturing, and then they sell to [Medtronic] USA." Trial Tr., May 11, 2009, pp. 10-11.

distribution rights other than to entities controlled or owned by Warsaw or Medtronic USA without Warsaw's consent; the distribution agreement does not limit Warsaw's right to refuse consent. PX 22 at MSD0718517. Medtronic USA holds "the co-exclusive right to enforce" the patents together with Warsaw, but Medtronic USA cannot assign its enforcement rights to others without Warsaw's consent. *Id.* By restricting Medtronic USA's ability to assign or transfer the "co-exclusive" rights, the distribution agreement preserves Warsaw's authority to determine whether others may distribute or sell products covered by the patents. *See Propat Int'l Corp.*, 473 F.3d at 1194.

The nature of the Warsaw and Medtronic USA business relationship created by the distribution agreement suggests Medtronic USA's role is Warsaw's distributor rather than its exclusive licensee. The distribution agreement imposes an obligation on Medtronic USA to purchase patented products from Warsaw and to use its best efforts to sell such products. PX 22 at MSD0718512. If Medtronic USA fails to perform those obligations, Warsaw may terminate the distribution agreement. PX 22 at MSD0718516. Medtronic USA's rights are more consistent with its role as an agent than co-owner of the patents. The agreement does not transfer sufficient exclusionary rights to confer standing on Medtronic USA to sue for infringement. Medtronic USA lacks constitutional standing to sue for patent infringement and will be dismissed with prejudice.

C. Damages and Injunctive Relief

In an action for patent infringement, a patentee may recover damages "adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court." 35

U.S.C. § 284. A patentee may also be entitled to injunctive relief. 35 U.S.C. § 283 (“The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.”). At the bench trial on damages and injunctive relief, plaintiffs sought three forms of relief: (1) an award of \$2,866,405 for lost profits to compensate for Medtronic USA’s sales of the Sextant System lost because of the infringement; (2) an award of \$1,327,866 for statutory royalties on sales of the Pivot System for which Medtronic USA did not claim lost profits; and (3) entry of a permanent injunction prohibiting Globus from selling the Pivot System. However, Warsaw is the only party entitled to recover for infringement.

1. Lost Profits

At oral argument, Warsaw acknowledged it is not entitled to lost profits; none will be awarded.

2. Reasonable Royalty

Warsaw is entitled to a reasonable royalty as compensation for Globus’ infringement. “Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.” 35 U.S.C. § 284. “The statute [35 U.S.C. § 284] is unequivocal that the district court must award damages in an amount no less than a reasonable royalty.” Dow Chem. Co. v. Mee Indus., 341 F.3d 1370, 1381 (Fed. Cir. 2003). Section 284 “does not mandate how the district court must compute [the reasonable royalty], only that the figure compensate for the infringement.” TWM Mfg. Co. v. Dura Corp., 789 F.2d 895, 899 (Fed. Cir. 1986). The “methodology of assessing and computing

damages under [the statute] is within the sound discretion of the district court.” Id. at 898. The only limitations on that discretion are: (1) that damages be no less than a “reasonable royalty for the use made of the invention by the infringer,” 35 U.S.C. § 284; (2) that damages adequately “compensate for the infringement,” id.; and (3) that the reasonable royalty be based on “sound economic and factual predicates,” Riles v. Shell Exploration and Prod. Co., 298 F.3d 1302, 1311 (Fed. Cir. 2002). A reasonable royalty is set by multiplying an appropriate royalty rate by the royalty base. The royalty rate is often expressed as a percentage of infringing sales resulting from the unauthorized use of the patented invention.

a. Royalty Rate

At the bench trial, the parties presented evidence of factors influencing the determination of an appropriate royalty rate. Warsaw claims the reasonable royalty rate is 15%; Globus claims the reasonable royalty rate is 6.5%.

A compensatory royalty rate must reflect the fair market value of the infringer’s unauthorized use of the patentee’s invention. The Federal Circuit recently explained:

A reasonable royalty may be based upon an established royalty, if there is one, or if not, upon the supposed result of hypothetical negotiations between the plaintiff and defendant. The hypothetical negotiation requires the court to envision the terms of a licensing agreement reached as the result of a supposed meeting between the patentee and the infringer at the time infringement began. A determination of the royalty stemming from a hypothetical negotiation is often made by assessing factors such as those set forth in Georgia-Pacific Corp. v. U.S. Plywood Corp., 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970).

Minks v. Polaris Indus., 546 F.3d 1364, 1372 (Fed. Cir. 2008).

In Georgia-Pacific, the court identified factors that may be relevant in determining a reasonable royalty rate. Georgia-Pacific, 318 F. Supp. at 1120. The court considers each factor

separately.

Factor 1: “The royalties received by the patentee for the licensing of the patent in suit, proving or tending to prove an established royalty.”

Warsaw, the patentee, is entitled to royalties under its license agreements with MPRO and Deggendorf. Under those agreements, Warsaw receives royalties of 23% of net sales by the licensee. However, since MPRO and Deggendorf are corporate entities related to Warsaw, the royalty rates provided under the license agreements do not prove a royalty rate established by an arms-length transaction. There is no evidence that Warsaw licensed the patents to unrelated parties (although it retained the right to do so), so there is no established royalty rate for the patents in suit. This factor has no effect on the royalty rate.

Factor 2: “The rates paid by the [hypothetical] licensee for the use of other patents comparable to the patent in suit.”

The parties did not present evidence of royalties paid by Globus for use of other patents comparable to the ‘929 and ‘422 patents. This factor has no effect on the royalty rate.

Factor 3: “The nature and scope of the [hypothetical] license, as exclusive or non-exclusive; or as restricted or non-restricted in terms of territory or with respect to whom the manufactured product may be sold.”

The parties agree that the nature of the license between Warsaw and Globus would have been non-exclusive. In the medical device industry, royalty rates are typically lower for non-exclusive licenses than for exclusive licenses because a licensor would demand a higher royalty rate in exchange for exclusivity. This factor weighs in favor of a lower royalty rate.

Factor 4: “The [hypothetical] licensor’s established policy and marketing program to maintain his patent monopoly by not licensing others to use the invention or by granting licenses under special conditions designed to preserve that monopoly.”

Although Warsaw granted licenses to Medtronic USA, MPRO and Deggendorf, Warsaw

demonstrated an established policy of refusing to license the patents in suit to competitors in the medical device industry. This factor weighs in favor of a higher royalty rate.

Factor 5: “The commercial relationship between the licensor and licensee, such as, whether they are competitors in the same territory in the same line of business; or whether they are inventor[s] and promoter[s].”

Warsaw and Globus directly compete against each other in the medical device industry. They manufacture similar products - the Sextant System and Pivot System - that are viewed by some surgeons as reasonable substitutes for each other. See Trial Tr., Nov. 10, 2008, p. 166. This factor weighs in favor of a higher royalty rate.

Factor 6: “The effect of selling the patented specialty in promoting sales of other products of the licensee; the existing value of the invention to the licensor as a generator of sales of his non-patented items; and the extent of such derivative or convoyed sales.”

The evidence of record demonstrates that surgeons who use either the Sextant System or Pivot System are likely to use other products manufactured by the same company. The patented invention generates valuable sales of products not covered by the patents. This factor weighs in favor of a higher royalty rate.

Factor 7: “The duration of the patent and the term of the [hypothetical] license.”

At the time of the hypothetical negotiation in August, 2005,²⁶ the ‘929 patent (issued March, 2003) and ‘422 patent (issued March, 2006) had most of their lives remaining. This factor weighs in favor of a higher royalty rate.

²⁶ Globus infringed the ‘929 patent as early as August 2005, when all components of the Pivot System were available for use and sale. Trial Tr., Sept. 24, 2008, p. 39. During the Summer of 2005, surgeons performed procedures using the Pivot System. Trial Tr., Sept. 23, 2008, p. 116.

Factor 8: “The established profitability of the product made under the patent; its commercial success; and its current popularity.”

Both the Sextant System and Pivot System have been commercially successful. Trial Tr., Sept. 17, 2008, pp. 79-80; Aside from fixed costs, both systems produce extremely high gross profit margins (in excess of 80%). This factor weighs in favor of a higher royalty rate.

Factors 9 and 10: “The utility and advantages of the patent property over the old modes or devices, if any, that had been used for working out similar results.”

“The nature of the patented invention; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the invention.”

The Sextant System is highly innovative, offers many medical advantages over the prior art and provides important benefits to patients and surgeons. These factors weigh in favor of a higher royalty rate.

Factor 11: “The extent to which the infringer has made use of the invention; and any evidence probative of the value of that use.”

Globus made significant use of the patented invention by manufacturing, marketing and demonstrating the infringing Pivot System. Globus benefitted from the infringement by earning substantial profits from sales of the Pivot System. This factor weighs in favor of a higher royalty rate.

Factor 12: “The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions.”

The price of allowance for use of the patented invention is not set by custom because competitors in the medical device industry do not typically license technology to each other. This factor has no effect on the royalty rate.

Factor 13: “The portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer.”

The patented features are important to surgeons and have driven sales of both the Sextant System and Pivot System. The high profitability of both systems is largely due to the patented technology. This factor weighs in favor of a higher royalty rate.

Factor 14: “The opinion testimony of qualified experts.”

The court credits the testimony of Dr. Vincent Thomas, Warsaw’s qualified expert witness, who testified that “an appropriate reasonable royalty rate would be 15 percent of Globus’ sales.” Trial Tr., Oct. 31, 2008, p. 138.

The court finds that a licensor, such as Warsaw, and a licensee, such as Globus, would have agreed upon a royalty rate of 15% if both had been reasonably and voluntarily trying to reach an agreement at the time the infringement began. A royalty rate of 15% reflects the amount a prudent licensee who desired to obtain a license to manufacture and sell products covered by the patents would have been willing to pay as a royalty and still make a reasonable profit.

b. Royalty Base

The evidence of record demonstrates that Globus generated \$13,901,795 in gross revenues from sales of components of the Pivot System between September 22, 2006 and September 30, 2008. Warsaw argues this amount constitutes the royalty base.

In his closing argument, counsel for Globus argued that the royalty base is not equal to the revenues from gross infringing sales, but should be determined by a three step process: (1) multiply the reasonable royalty rate (determined after consideration of the Georgia-Pacific factors) by Warsaw’s unit cost of production for each component of the Sextant System; (2)

multiply the resulting numerical product from Step 1 for each Sextant System component by the number of units sold by Globus for each corresponding component of the Pivot System; and (3) aggregate the resulting numerical products from Step 2. Trial Tr., May 11, 2009, pp. 40-45.

Counsel explained that, assuming a reasonable royalty rate of 15%, application of this formula would yield an “effective” royalty rate of 0.39% once the sum calculated in Step 3 is divided by Globus’ gross revenues from sales of the Pivot System.²⁷ Id. at 44. Under this formula, Globus contends the appropriate amount of compensatory royalties should be \$54,061 (applying a 15% royalty rate) or \$23,464 (applying a 6.5% royalty rate).

Globus’ argument is frivolous, incoherent, contradicted by its own expert and contrary to authority. On direct examination, Dr. Scott Hampton, Globus’ expert on patent valuation and infringement damages, testified that Globus’ total infringing sales “represents the royalty base.” Trial Tr., Nov. 10, 2008, p. 126. When Globus’ counsel referred Dr. Hampton to DDX506, reflecting “total infringing sales” of “\$13,901,795,” Dr. Hampton stated there was no dispute as to this calculation. Id. The same exhibit reported Dr. Hampton’s finding that reasonable royalty damages of “\$903,617” were adequate to compensate for infringement. DDX506.

The result produced by Globus’ royalty formulation is not a “royalty base” as Globus claims. The fractional “effective” royalty rates produced by Steps 1 and 2 nullify the court’s application of the Georgia-Pacific factors; the formula is contrary to controlling law.²⁸

²⁷ Counsel explained that application of a reasonable royalty rate of 6.5% would yield an “effective” royalty rate of 0.17%. Trial Tr., May 11, 2009, p. 45.

²⁸ Globus also argued the jury’s finding of direct infringement rather than contributory infringement requires reduction of damages to a nominal amount. This argument was contradicted by the testimony of Globus’ own expert on patent valuation and infringement damages.

Employing mathematical commands such as addition, multiplication and division without any discernable reason, the formula calculates compensatory damages that are minuscule when compared to the reasonable royalty to which Warsaw is entitled. Globus' own expert opined that a reasonable royalty of \$903,617 would compensate for infringement, but Globus' incomprehensible mathematical formula results in \$23,464 as the appropriate quantum of damages.²⁹

The evidence of record demonstrates a royalty base of \$13,901,795. Applying the royalty rate of 15% to the royalty base of \$13,901,795, Warsaw is entitled to a reasonable royalty of \$2,085,269.20.

c. Pre-Judgment Interest

Under 35 U.S.C. § 284, Warsaw is also entitled to pre-judgment interest. "In federal question cases, the rate of pre-judgment interest is committed to the discretion of the district court." Sun Ship, Inc. v. Matson Navigation Co., 785 F.2d 59, 63 (3d Cir. 1986). The court may be guided by the post-judgment interest rate set forth in 28 U.S.C. § 1961. Sun Ship, Inc., 785 F.2d at 63. Other courts within this circuit have generally followed this approach. Anderson v. CONRAIL, 2000 U.S. Dist. LEXIS 15978, *13 (E.D. Pa. Oct. 25, 2000) (Bartle, C.J.). 28 U.S.C. § 1961(a) provides in relevant part, "Such interest shall be calculated from the date of the entry of the judgment, at a rate equal to the weekly average 1-year constant maturity Treasury yield, as published by the Board of Governors of the Federal Reserve System, for the calendar week

²⁹ Globus argued the reasonable royalty due Warsaw should be a fraction of the reasonable royalty due Medtronic USA. Since a reasonable royalty compensates for the *infringer's* use of the patented invention, see 35 U.S.C. § 284, the patentee's unit cost of production and revenues from sales of patented goods are irrelevant to the calculation of the royalty base.

preceding the date of the judgment.”

Warsaw argues, “Pre-judgment interest should be awarded at the prime rate, compounded annually, and may be computed after the award of the judgment, as part of the final accounting.” Pls. Post-Trial Br., p. 10. Warsaw cites no authority for the calculation of pre-judgment interest at the prime rate; such a calculation is inconsistent with 28 U.S.C. § 1961(a), providing that interest be calculated at a rate equal to the weekly average 1-year constant maturity Treasury yield. Warsaw may submit a motion for accrued interest at the rate provided under 28 U.S.C. § 1961(a) from September 22, 2006 to the date of judgment. Post-judgment interest will follow by statute.

2. Injunctive Relief

The Patent Act allows injunctive relief upon a finding of patent infringement. “The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.” 35 U.S.C. § 283. A district court must consider the well-established principles of equity before enjoining an infringer from practicing the patented invention. “A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.” eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006).

Warsaw, the only party with constitutional standing, did not present evidence of irreparable harm. The only evidence presented at trial pertaining to Warsaw was testimony from

plaintiffs' corporate designee, who could not describe the nature of Warsaw's business:

Q. What's the business of Warsaw Orthopedics?

A. Again, Warsaw Orthopedics is one of the legal entities, if you will, under the Medtronic umbrella, and I think all that information has been provided, but I can't speak to the exact specifics of each one of these entities.

Q. When you say legal entity, you're referring to it being an independent and separate corporation, correct?

A. Again, I don't have specific knowledge of that.

Q. Do you know what it does?

A. Warsaw Orthopedics?

Q. Yes.

A. I think it's one of the holding companies for the patents, but again, I don't have great knowledge on that, I apologize.

Trial Tr., Oct. 30, 2008, pp. 184-85 (cross-examination of Doug King).

After Globus' assertion of the standing defense, Warsaw was ordered to state with specificity the evidence it would present if the record were re-opened; Warsaw proffered no evidence of irreparable harm. Warsaw argued it is entitled to injunctive relief based on trial evidence of injuries to Medtronic USA.

Medtronic USA presented evidence of "[irreparable] harms that defy monetary quantification and that controvert [Medtronic USA's] long-term goals, including loss of access to surgeons, loss of the opportunity to sell other products for use in the same Sextant surgeries . . . , loss of the opportunity to use these flagship products to sell surgeons other products for use in non-Sextant surgeries, eroded market share, loss of goodwill, and injury to [Medtronic USA]'s reputation as an innovator in the area of minimally invasive surgeries." Pls. Post-Trial Brief at

12. But Warsaw is a manufacturer of medical devices, not a distributor;³⁰ it is unlikely that Warsaw suffers the same irreparable injuries as Medtronic USA. There is no evidence that Warsaw would have had access to surgeons or the opportunity to sell the Sextant System (or other products) to hospitals that purchase surgical equipment. Warsaw presented no evidence of its market share or the loss of good will. The evidence of record does not support entry of a permanent injunction. Warsaw failed to present evidence of irreparable harm, so the court cannot consider the balance of hardships between Warsaw and Globus. The parties presented evidence on whether issuance of an injunction would be contrary to the public interest, but since no injunction will issue for lack of evidence of irreparable harm to Warsaw, the only plaintiff with standing, the court need not decide the matter.³¹

D. Rule 52(a)(1)

Federal Rule of Civil Procedure 52(a)(1) provides in relevant part, “In an action tried on the facts without a jury . . . , the court must find the facts specially and state its conclusions of law separately. The findings and conclusions . . . may appear in an opinion or a memorandum of decision filed by the court.” This opinion constitutes the court’s findings and conclusions following the bench trial on damages and injunctive relief.

³⁰ The evidence of record shows that Warsaw manufactures medical devices and Medtronic USA distributes medical devices. See PX 22 at MSD0718511 (“Warsaw is in the business of manufacturing medical devices and . . . [Medtronic] USA is in the business of selling medical devices”).

³¹ Although Medtronic USA lacks constitutional standing and cannot recover for infringement in this action, it did present evidence of irreparable harm. Should Medtronic USA acquire the necessary exclusionary rights or title to the patents from Warsaw, Medtronic USA could then file a civil action for future infringement and injunctive relief.

III. CONCLUSION

Plaintiffs' request to re-open the record is granted in part. PX 17, PX 20, PX 21 and PX 22 are admitted into evidence. Plaintiffs' request is denied in all other respects. Plaintiffs Medtronic Sofamor Danek USA, Inc., Medtronic Puerto Rico Operations Co. and Medtronic Sofamor Danek Deggendorf, GmbH lack constitutional standing and are dismissed with prejudice. Warsaw Orthopedic, Inc. is entitled as compensatory damages for infringement of the '929 and '422 patents a reasonable royalty of \$2,085,269.20 plus pre-judgment interest. No injunctive relief will be awarded.

An appropriate order follows.